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Reflexive governance in biobanking: on the value of policy-led approaches and the need to recognise the limits of law

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Abstract

Although a few jurisdictions around the world have legislated in response to the phenomenon of biobanking, the far more common response has been policy-led with funders and other stakeholders initiating multi-level policy initiatives to guide biobanking practice. An example of this is UK Biobank which has developed and operates according to an Ethics and Governance Framework. Such an instrument has no basis in law and yet it has played a crucial role in the set up and on-going management of the resource. It will continue to do so as related policies emerge, such as access and intellectual property policies. Numerous biobanking initiatives have similar high-level policy documents that guide decisions and practice. These are often framed as a commitment to participants, researchers and society more broadly and invoke notions such as the public good and the public interest. As such, they serve as a benchmark against which to measure a biobank's performance. Moreover, policies become an important means by which biobankers are held accountable. This article critically analyses this policy-driven phenomenon asking how effectively policy - often as an alternative to law - serves to police and to promote biobanking. It argues that a policy of reflexive governance – defined and developed herein – can best meet the challenges faced by many biobanks and without the need for recourse to law.

Keywords

biobanks; reflexive governance; law; policy; ethics

Introduction

Much has been written about the so-called unique and challenging features of biobanks, including issues relating to the nature, scope and adequacy of consent (Otlowski, 2009); the importance of protecting privacy (Taylor and Townend, 2010; Schörder et al, 2010); the impossibility of guaranteeing anonymity (Lowrance and Collins, 2007); the eternal quest to establish and maintain trust (Sutrop, 2007); and the inadequacy of existing legal mechanisms to accommodate some or any of these features (Gibbons, 2007). This article does not seek to repeat any of these discussions. Rather, it offers perspectives on two features of biobanking which are far more crucial to the success of biobanks: (i) the challenge of designing effective policies in the establishment, maintenance and long-term operation of a biobank, often instituted in the absence of biobank-specific laws, and (ii) the role of reflexive governance as an optimal means to institute such policies and to help ensure that biobanks deliver on their stated objectives. Many of the insights herein are drawn from the author's experience of serving as the Chair of the UK Biobank Ethics and Governance Council from 2006-2010. Nothing that is said should be taken to reflect the views of the Council, UK Biobank, or its funders.

Andrews (2001) and Knoppers (2009a) have mapped policy approaches towards the regulation of genomics research over the last two decades, suggesting ways in which our thinking has shifted, and needs to shift, to accommodate new and emerging practices, especially with the advent of biobanking. Thus, while Andrews compares the (individualistic) medical, public health and fundamental rights approaches adopted from 1990-2000, Knoppers characterises these as static systems from which we have moved on to appreciate the need for a complex systems approach; this is typified by research governance policies which promote openness and sharing (communalism), population-based participation in research (citizenry) and joined-up initiatives to realise the research promise (convergence). This article argues that more work needs to be done on understanding the possibilities for policy development that capture and reflect the on-going challenges of biobanking which, by their very nature, are not fixed in any cultural or temporal way. These challenges make biobanking and the law uneasy bedfellows. Fixed legal responses tend to reflect a particular state of science or ethical thinking at a particular time; this is not adequate to accommodate the kinds of paradigm shifts identified by scholars like Andrews and Knoppers. More fundamentally, it is not clear that law or legal architectures can adequately set up the necessary adaptive systems of behaviour that are required for the creation and operationalisation of biobank policies that are fit for purpose over time. It is suggested that the answer to this lies in the model of reflexive governance proposed herein.

The role of policy in biobanking

There has been a considerable amount of existential angst generated around the question of what constitutes a biobank (Shickle, Griffin and El-Arifi, 2010). None of this has generated any clear consensus about their nature nor about what is to be done with them (Stranger et al, 2008), save to highlight that biomedical collections of samples and data held for treatment and/or research purposes are heterogeneous: ‘...differing markedly in their origins, design, size, content, duration, ownership and purpose’ (Gibbons, 2007). For those interested in identifying common policy or regulatory objectives, it is beyond trite to confirm that one size does not fit all (Mitchell, 2011). Yet, this is not to suggest that we cannot discern common challenges for biobanks which will necessarily impact upon, and which should shape relevant policy and regulatory agenda. Three challenges in particular can be identified.

Diversity

The heterogeneous nature of biobanks is both a benefit and a challenge. Heterogeneity is key to both the promise and the problems for science and science policy. These coalesce around one stark fact about the importance of these collections with respect to the overarching objective of improving human health: the said objective cannot be realised if diversity of approaches – towards the conduct of the science and its governance – is too great. The irony is that while the diversity of the samples and data *within* collections is potentially enriching of our understandings of human health and disease, diversity of scientific methods or governance arrangements *between* collections will stand to thwart this understanding if biobanks cannot link up and learn from each other, ideally on a global scale. There are, therefore, dual elements to the diversity challenge: (i) designing-in interoperability both with respect to scientific and governance approaches, and (ii) designing-out approaches that are restrictive of sharing, cooperation, flexibility and mutuality (Gottweis and Zatioukal, 2007; Fullerton et al, 2010).

Uncertainty

Many biobanks have a clear purpose and end point, but many do not. Indeed, the biobank model that has caused most consternation is that which is deliberately designed to be open-ended: to construct a research resource in the spirit of ‘build it and he will come’. The challenge is that those with stewardship responsibilities for the biobank do not know who *he* will be, where *he* will come from, what *he* will want to do with the resource, to what ends or with what consequences. This gives rise to an immediate tension between, on the one hand, (i) establishing policies and procedures to *protect* adequately the interests of participants who have contributed to the establishment of the resource, and, on the other hand, (ii) establishing policies and procedures which *promote* the use of the resource as widely as possible. Mechanisms that can effectively secure the dual elements of the uncertainty challenge are not readily available. Most notably, while laws exist, or can be created, to protect individuals’ rights and interests - and indeed to protect against harm to the public interest - law as a social tool has

a far less salubrious record in promoting public interest as such (Laurie et al, 2010).

Temporality

The third challenge is inherently linked to the first two. This is the temporal challenge of establishing resources the benefits of which might not be realised for a considerable time, and which most probably will only be enjoyed by generations to come. The temporal challenge arises both because of scientific and natural restraints – the time needed to generate sufficient data on instances of disease and/or through overcoming the diversity challenge – and because many biobanks are purposefully designed as long-term endeavours, generating uncertainties such as those outlined above. As with the other challenges, the temporal challenge has two potentially competing elements: (i) ensuring the longevity of the biobank, for example through carefully managed access policies & arrangements and stewardship of depletable elements of the resource, and (ii) ensuring that governance policies and mechanisms remain fit for purpose over time with respect to both the private and public interests that are – or might be – at stake.

A Good Governance Framework

From this discussion we can identify an outline framework against which biobank policies and design can be built and measured. A good governance framework will be one which contains features:

- (i) designing-in interoperability with respect to scientific and governance approaches,
- (ii) designing-out approaches that are restrictive of sharing, cooperation, flexibility and mutuality,
- (iii) establishing policies and procedures to protect adequately the interests of participants,
- (iv) establishing policies and procedures to promote actively the use of the resource in keeping with its original purposes,
- (v) ensuring the longevity of the biobank through carefully managed access policies & arrangements and stewardship of the resource, and
- (vi) ensuring that governance policies and mechanisms remain fit for purpose over time.

The implementation of policies designed to achieve these objectives must be guided by principles that ground the framework. These will also assist in resolving tensions or conflicts between these objectives as concrete expressions of the challenges faced by a biobank. It is submitted that three principles are essential to guide deliberation and action for a good governance framework for biobanks. These are:

(1) The principle of integrity of purpose

It is often said that trust is a cornerstone of good and effective biobank governance (Sutrop, 2007). At the root of every trustworthy relationship is an expectation that those in whom we trust will do what they say they will do and will act in ways consistent with any undertaking to us. The principle of integrity of purpose is extremely important to many aspects of working of a trustworthy biobank; it suggests that the resource will be managed to bring about the core objectives for which it was established, for example – as a disease register or to promote the health of future generations. Furthermore, this principle can help to promote trust and to set realistic expectations for all stakeholders in the biobanking enterprise, and particularly the participants. Importantly, the principle of integrity of purpose does not dictate any particular approach to any particular aspect of the operation of a biobank, for example by mandating informed consent or by requiring absolute anonymity of personal data. Rather, the principle focuses on the relationship between those with responsibility for the biobank and those who have contributed to it or might expect to benefit from it, which could include society at large.

The principle requires both that the biobank be founded with integrity – at base, that the initiative is scientifically sound and ethically robust – and that it is managed with integrity and in keeping with its origins and any original undertakings. It requires clarity and veracity with respect to what participants can expect about the protection of their interests. This will mean, for example, that the true nature and limits of consent or privacy protections must be made explicit. It is now well-rehearsed that informed consent and absolute anonymity are not achievable states for many, if not all, biobanking projects (Otlowski, 2007; Lowrance and Collins, 2007). It does not follow, however, that these projects are not viable or of questionable worth. Rather, the principle of integrity of purpose requires that participants (and others) understand the true nature of the proposition being made in light of the purpose that is being sought and that the realisation of the purpose objectives might require trade offs over time (Meslin, 2010).

(2) The principle of proportionality of action

The imperative both to protect participants' interests and to promote public interests can give rise to conflict and tension, although this is by no means inevitable. It should not be forgotten, for example, that the protection of individual rights and interests is equally an important public interest. Moreover, the principle of proportionality of action can serve to militate against arriving at stalemate because it requires that conduct that might impact negatively on a countervailing set of interests should only occur: (i) to further the legitimate purposes of the resource, as above, and (ii) when it is effective, necessary and proportionate to so act. Thus, risks to privacy – while always present and undoubtedly increased by sharing of data – can be seen as acceptable so long as the imperative to share is demonstrated, the benefits

to the public interest are articulated, and the relative risks to privacy are minimised.

It is important to note another essential role that the principle of proportionality of action has to play in biobank governance arrangements. As the next section demonstrates, there is no shortage of laws or quasi-legal instruments that apply to the governance of biobanking and genomic research. Indeed, in 2009 evidence to the United Kingdom's House of Lords' Science and Technology Committee indicated that those wishing to conduct genomic research in that country were required to navigate "...43 relevant pieces of legislation; 12 sets of relevant standards; [and] 8 professional codes of conduct..." (House of Lords, 2009). A recent report from the Academy of Medical Sciences, set up to assist the British government ' [to] consider the bureaucracy affecting research... and bring forward plans for radical simplification in light of the Academy's review', has argued strongly that a system of *proportionate governance* is required. This must:

(i) safeguard well-being of participants, (ii) facilitate high-quality health research to the public benefit, (iii) be proportionate, efficient and coordinated, and (iv) maintain and build confidence in the conduct and value of health research through independence, transparency, accountability and consistency (Academy of Medical Sciences, 2011).

The Academy has advocated the establishment of a single National Research Agency to delivery on such objectives. Few would quarrel either with the spirit or content of these recommendations. What is not clear is how this might be achieved in practice, nor how this might require adaptation in the context of biobanks. This brings us to the third and final principle underpinning the good governance framework proposed in this paper.

(3) The principle of reflexivity of approach

We have seen that the core challenges facing biobanks arise from their diversity, their longevity and the uncertainty that underpins their future direction. The principle of reflexivity of approach requires that we devise mechanisms to allow biobanks to proceed in the face of this uncertainty and that we learn from experience along the way to deliver effective governance that meets the six objectives outlined above. This is a non-trivial task. We simply do not know what is in store for these resources and their participants, nor can we effectively second-guess what value might be realised from their operation, nor what further challenges might be generated by their continued existence. What is to be done?

We could attempt public engagement exercises to inform policy in this regard, and this might assist in choosing between a range of possible policy options (cf – Haddow, Cunningham-Burley and Murray, 2011). As Häyry and Takala have suggested:

"Public authorities have at least five strategies by which they can try to take in account people's opinions regarding activities in the

social realm. They can leave things as they are and assume that market forces and common decency will keep the activities in question under control. They can encourage the self-governance and professionalism of the parties involved in the practice, and hope that their business sensitivity and integrity prevent immoralities and damage. They can regulate the activity by policies which make it profitable for entrepreneurs to respect majority opinion. They can find guidance in the existing body of law, and inform all those involved of the probable legal consequences of malpractice. Or they can create new laws, either to clarify the legal situation or to develop completely new rules to regulate the activity. The choice of the strategy should, in democratic societies, reflect the views prevalent among the population.” (Häyry and Takala, 2007, p.252)

This appraisal of options gives rise, in turn, to a number of questions. First and foremost, does the appraisal exhaust all the possible options? We shall return to this matter in due course to suggest that the answer is no. Second, although recourse to law features quite readily, it is by no means dominant; are there reasons, therefore, to prefer non-legal routes over legal ones, or vice versa? Finally, what does it mean ‘to reflect the views prevalent among the population’; importantly, what role, if any, should such attempts have in biobank governance?

The second half of this article will attempt to answer these questions. It proceeds in two sections. The first section suggests that there are limits to law and what legal frameworks can achieve, especially as measured against the six objectives of the good governance framework and its three underlying principles. Central to these principles is the principle of reflexivity of approach. The article ends with a normative argument that what is required in this context is the development and adoption of *reflexive governance* systems for the regulation of biobanks. The example of UK Biobank is offered as a possible model from which wider lessons can be learned.

The limits of law

For lawyers, recourse to law is a first natural reaction to new social challenges. This is especially true in the context of biobanking when so many of the issues have been declared to be novel, unanticipated, potentially harmful and inadequately regulated by existing legal mechanisms (Cutter et al, 2004, Gibbons, 2007). Yet, experiences of bespoke legal frameworks to regulate biobanking practices suggest neither effective nor necessary protection of the interests at stake. The earliest and most infamous example – the Icelandic Act on Biobanks no.110/2000 - ended up being declared unconstitutional (Gertz, 2004). Other less controversial examples include Estonia (Human Genes Research Act 2000), Latvia (Human Genome Research Law 2003), Sweden (Biobanks in Medical Care Act 2002: 297), Norway (Act

Relating to Biobanks 2003), Portugal (Law 12/2005, of 26 January, on personal genetic information, provisions on genetic databases) and Spain (Law 14/2007, of 3 July, on Biomedical Research, title on biobanks).

There is little that could be described as uniformity of approach in these examples, albeit that they do serve to clarify certain rights and responsibilities with respect to biobanks in the individual countries (Taylor and Townend, 2010). Kaye (2006) has helpfully laid out what could be contained in a uniform European approach, although ultimately the tentative conclusion is that ‘...[a] “hard-law” regulatory approach may not achieve the uniform regulatory framework for biobanks that scientists and researchers seek.’ Moreover, it is acknowledged by Kaye and others that no legal intervention should be introduced without some assessment of how this might impact on biobanks which are already operational. And herein lies the rub – the majority of biobanking practice goes on without the intervention of bespoke law. This is not to suggest that there is a legal vacuum; indeed, arguably, quite the opposite is true – consider once again the example from the House of Lords report on Genomic Medicine.

The core concern about introducing biobank-specific laws is two-fold: first, as Wallace et al (2008) have highlighted, we should be very careful not to repeat practices of genetic exceptionalism of the 1990s, most especially at the population level (see also Holm, 2009); second, and as an instance of the principle of proportionality of action, we should only add to regulatory burden if it can be demonstrated that legal provisions are necessary, proportionate and likely to be effective. Many publications have revealed holes in existing legal provisions (see for example Gibbons, 2007), but it does not necessarily follow that new or more law is required. In fact, science has been getting on with the job in biobanking initiatives around the world while lawyers have fretted over the adequacy of existing norms or the need for new frameworks (Cf - BBMRI and P3G as examples of productive interdisciplinary working in this regard).

As the good governance framework outlined in this article suggests, law might be called upon both to protect and to promote core interests engaged in biobank practices. The fact that responsible science is often being conducted against the backdrop of existing legal frameworks and without the need for further specific legal provision speaks volumes. Notwithstanding, it must be recognised that law has played its part in getting us to this stage and in helping to ensure that the science in question is, indeed, responsible. The role of ethical review mechanisms now helps to protect against the worst vagaries of poor science, albeit that this system has come in for much criticism over the years as unduly burdensome, a possible hindrance to research and not necessarily conducive to more ethically robust science (Knoppers, 2009b). Ashcroft (2003) pinpoints part of the problem thus:

“Far from the classical sense of regulation which defines a commonly agreed goal, and draws up a regime and authority to ensure that private activity tends in that direction, here the regulators are not sure what the goal is.” (p56)

This is made worse because ethics committees are put in a position of having to balance ethical reflection with acting as a gatekeeper to research; many of the associated legal architectures further compound the problem by establishing bureaucratic, inspectorate-driven oligarchies of science regulation. The cumulative effect is that we have lost sight of ethics as a means to assist reflection on genuine dilemmas, in favour of a tick-box mentality which - albeit driven by the best of motives - fosters unhealthy suspicion and favours procedure and caution at the expense of real engagement with the issues at hand. Something gets lost in the process – most notably, that the issues are not simply about the protection of research participants’ interests but also about the promotion of core interests and values that are in the public interest.

If at the heart of the biobanking enterprise is the need to promote issues such as trust and the public interest, it is not clear that laws alone can deliver on this task. The central policy mechanism that is required is one capable of anticipating which challenges might arise and building systems that are sufficiently flexible and adaptive to respond timeously. It is suggested here that a system of reflexive governance represents such a system.

Reflexive governance

A system of reflexive governance is not merely a mechanism of foresighting when we are uncertain about what the future holds for a particular area of science (Williams, 2006); nor is it a mechanism of anticipatory governance which tries to second-guess future pathways to prepare us for the road ahead (Karinén and Guston, 2010). Rather, reflexive governance is both about partnership in governance in the face of future uncertainty and the facilitation of mutual learning for experience over time. According to Vincent-Jones and Mullen:

‘Stated in positive terms, the attainment of reflexivity requires that actors have the capacities and the competencies to participate in and contribute to social learning; that they communicate and interact in relational and deliberative ways; that they engage in and learn from experimentation through collaborative forms of joint enquiry; and that their learning is informed by cognitive processes entailing the adjustment and redefinition of frames, representations and collective identities.’ (Vincent-Jones and Mullen, 2010)

On this conception the focus is on attitude and approach – it is about the governed and those governing being reflective, receptive and responsive. As the same authors note: ‘[t]he legal framework by itself is incapable of facilitating the conditions necessary to promote a sufficiently receptive and deliberative orientation on the part of the relevant actors’ (p.153). Rather, ‘...fully reflexive governance is dependent on deliberation and openness to alternative possibilities in the framing of problems and the suggestion of solutions...’ (p.175)

A key question that arises then is, who are the relevant actors? In the context of biobanks, this question might receive a broad reply and – beyond those

responsible for the biobank itself - might include funders, participants, regulators, ethics committees or the wider society itself. On this view, however, we risk developing a recommendation that is simply not workable in practice. Moreover, this fails to capture the notion of partnership in governance which, I suggest, must also lie at the heart of any system of reflexive governance.

Central to this partnership must be some entity that acts as a critical friend to the biobank. Like any such relationship, it will be based on trust and mutual respect and the common desire to see the biobank achieve its purpose; in other words, trust will stem from a common commitment to the *principle of integrity of purpose*. Also, like any critical friend, the parties will sometimes disagree over what is the right thing to do; and here the *principle of proportionality of action* will help to guide and temper behaviour. And, as with all relationships, we do not know what lies ahead for us; and here the *principle of reflexivity of approach* offers a mechanism for genuine engagement over issues and dilemmas as and when they arise, framed by the common objectives of the biobanking exercise itself.

Importantly, this mechanism of reflexive governance must operate in tandem with the development of the scientific endeavour – ensuring, like any critical friend, that advice and guidance is available at every stage of the joint journey. In this way, a system of reflexive governance can operate to add value where none currently exists. It is about encouraging a culture of cooperation and compliance rather than monitoring non-compliance (Academy of Medical Sciences, 2011). Thus, it is neither a version of top-down regulation nor a system of up-front ethical approval of a scientific protocol. Reflexive governance provides a system of organic policy development over time. This is both responsive to the demands of the project and, at the same time, it can take in account a range of values and interests, and most importantly those of participants in the project, which can – and will – change over time.

The example of UK Biobank

I have argued elsewhere that UK Biobank is an example of reflexive governance in action (Laurie, Bruce and Lyall, 2009b). In the current context, we can consider how this example reflects the good governance framework outlined above and also how it is underpinned by the three core principles advocated in this work.

UK Biobank has been established as a major research resource containing genetic, health and lifestyle information, as well as samples, from over 500,000 people in the United Kingdom, aged between 40 and 69 at the time of recruitment (UK Biobank, 2011). The purpose of UK Biobank is to support a diverse range of health-related research intended to improve the prevention, diagnosis, and treatment of illness, as well as to promote health throughout society. It is envisaged that the resource will be maintained as openly as possible to encourage wide-ranging applications from around the globe; the project will be blind to whether applicants come from a

commercial or a public sector background; the sole consideration about pedigree will relate to the calibre of the research to be conducted and the trustworthiness of applicants to provide safe systems to protect participants' interests and to conduct science in keeping with the original broad purposes of the endeavour – that is, health-related research in the public interest.

UK Biobank is subject to a plethora of existing legal provisions protecting participants' interests and has not required any legislative intervention in this regard (Laurie, Bruce and Lyall, 2009b). The real challenge has been in designing internal governance mechanisms to promote the core purposes of the resource, and in this respect the project has been ground-breaking in two respects: (1) its Ethics and Governance Framework and (2) its Ethics and Governance Council.

The Ethics and Governance Framework (EGF) is a publicly-available living instrument from UK Biobank which makes explicit the core undertakings of UK Biobank to its participants, researchers, and wider society. As such, this document directly embraces both the principle of integrity of purpose and the principle of reflexivity of approach. The former is engaged by articulating – deliberately and very broadly – the purposes in pursuit of which the resource will be run. The latter is invoked by envisioning the EGF as an organic policy device that will be revisited and revised over time as the project progresses and as new or unforeseen circumstances develop. The EGF will remain throughout as a publicly-facing expression of what UK Biobank can be said to stand for.

UK Biobank's critical friend is the independent and permanent Ethics and Governance Council (EGC). This was established in 2004 in the set-up phase of UK Biobank. Since its inception the work of the EGC has been evolving, reflecting the necessarily organic nature of its role. For example, in the early stages before recruitment the EGC's role was primarily advisory and related to associated recruitment policies and procedures, the content of information leaflets and consent forms etc. As recruitment got underway, the EGC also assumed a monitoring role pertaining to complaints and enquiries, information security provisions, proposals for follow-up and implementation of the project's plans for on-going engagement with participants. Latterly, the EGC has also taken on a foresight and development role with respect to the UK Biobank access and intellectual property procedures, working with UK Biobank through an EGC sub-group. The practice throughout has been to facilitate and foster an open dialogue with UK Biobank through regular meetings, sub-groups, public meetings and the publication of minutes.

A number of examples of reflexivity as defined above can be identified as arising from this governance mechanism. These can be found in the public minutes of the EGC. Two examples are particularly pertinent.

(a) Revision of the EGF

The original version of the EGF contained the following option for participants to withdraw at any time and for any reason:

“No further use”: In addition to no longer contacting the participant or obtaining further information, UK Biobank *will destroy all of their health-related information* and samples collected previously (although the participant would be told that it may not be possible to trace and destroy all distributed anonymised sample remnants) [emphasis added]

Over time, and as UK Biobank began to develop its IT systems, it became clear that it would not be possible to destroy *all* data held. System designs were such that some data had to be retained for the integrity of audit systems and to demonstrate that the systems themselves worked effectively. After discussion with the EGC, the following revision was made to the EGF:

“No further use”: ...in addition to no longer contacting you or obtaining further information about you, *any information and samples collected previously would no longer be available to researchers*. UK Biobank would destroy your samples (although it may not be possible to trace all distributed sample remnants) and *would only hold your information for archival audit purposes*. (emphasis added)

The Council also recommended that the information leaflet to new participants be revised and that these changes be brought to public attention via the UK Biobank and EGC web pages. The question also arose as to whether persons already recruited should be approached directly and informed. After joint consideration and reflection it was agreed that this was not necessary. The justification was that the integrity of the original promise to participants – that their data and samples would not be used for further research – had not been compromised; nor was the absolute right to withdraw affected in any way. The course of action agreed upon was agreed to be proportionate to the new circumstances that had arisen.

(b) Future use of the resource

The purposes of UK Biobank are potentially very wide. It is not unusual for the EGC or UK Biobank to receive queries about possible future uses of the resource. One such query arose in 2009 concerning applications to access the resource to carry out research into somatic-cell nuclear transfer. The query which was raised was why the EGC did not take a stand on the hypothetical possibility of such an application arising, given the current climate of concern surrounding this particular branch of science (Jones and MacKellar, 2009).

The EGC responded by re-iterating the broad purposes of the project and the robust governance mechanisms that are in place to oversee all future applications. It confirmed that the breadth of purpose would not automatically rule out such an application (which is not the same as saying that such an application would ever be granted access). The EGC pointed out further that, as an independent body, it is not in a position to control access to the UK Biobank resource. Moreover, it would not be appropriate for the Council to second-guess future social mores (Laurie, 2009a). Notwithstanding, the Council did note that if ever such an application were

to arise then the UK Biobank system of governance would ensure that appropriate dialogue would arise at the appropriate time. Furthermore, a core objective of the Council is to monitor that the original consent of participants – to participate in UK Biobank – is being respected. Any concern that this was not the case would result in a recommendation that further, more specific consent be sought. Other options might include recommendations for public engagement activities to test the moral waters of the time. In this way, the principles of integrity of purpose and reflexivity of approach can be seen to be in operation here. This is a paradigm example of what reflexive governance can provide.

Another advantage of a reflexive governance approach is that it can serve to engender healthy *institutionalised distrust* as a means to foster trust in the enterprise as a whole. For example, Ruyter et al (2010) have suggested that mechanisms which are internally regarding and self-critical of policies and procedures can help to assure outsiders, or in the context of biobanks – participants themselves, of the robustness of the checks and balances that are in place. Supportive critical engagement lies at the heart of reflexive governance.

This having been said, reflexivity – or reflectiveness – might not come easily to some actors, especially those whose acts are under scrutiny. This is a capability that must be learned, for otherwise it might result in ‘defensive strategies’. For some, such as Schön (1994), this learning can arise merely from inherent capacity and an attitudinal openness to reflection. For others, such as Lenoble and Maesschalck (2010), more is required of the reflexive governance approach, for example, a positive engagement by each actor with the form of relationship that its identity has taken in the past and that which it might take in the future. This enables a necessary transformation towards an ‘ability-to-do’ what is required of the actor in its future capability.

It must also be recognised that trust between the relevant actors is not merely a matter of transparency as is so often claimed in other contexts. Trust here stems from the common commitment to the principle of integrity of purpose while the principle of reflexivity provides a means to realise this and to found a relationship for moving forward. Furthermore, and as I have argued elsewhere:

‘...an obligation to express clearly one’s value-stance necessitates reflexivity, that is, self-reflection on what exactly it means to hold such a value and where its limits lie. It is in the territory between value positions that effective, reasonable, legitimate and legitimated policy is to be found. (Laurie, Bruce and Lyall, 2009b)

The limits of reflexive governance

It would be disingenuous not to consider some of the possible limits of a reflexive governance approach. Three questions, in particular, are likely to arise in the mind of the reader. These are:

- (1) Can participants or other stakeholders be involved in the reflexive governance model, and if so, how?
- (2) Can the reflexive governance model work in the absence of hard law sanctions?
- (3) Can the reflexive governance model work for other biobanks?

Can participants or other stakeholders be involved in the reflexive governance model, and if so, how?

Proponents of reflexive governance in other sectors, such as energy, agriculture or transportation strongly favour 'participatory' or 'deliberative' forms of reflexivity, although it is becoming increasingly apparent that real challenges lie in 'maximising the normative expectations of all of the actors' (Lenoble and Maesschalck, 2010, p14). It is certainly the case that the biobanking environment has lots to learn from nonmedical sectors in terms of improving its governance regimes (Yarborough, 2009), especially with respect to public or participant involvement exercises (O'Doherty and Hawkins 2010). Space does not permit a full discussion of this phenomenon but a few points are worth highlighting.

Perceptions about an 'agency gap' in many biobank governance regimes – which is often taken to mean an absence of direct representation for participants on biobank decision-making bodies – has led some to argue that this is a necessary requirement of a good governance framework. Winickoff (2007, 2009), for example, advocates a shareholder model of biobank governance, akin to a corporate model of representation and voting through a participant representative body that is oriented to addressing the perceived democratic deficit. This might work well in the case of biobanks designed specifically to address the health needs of its participants, but it is less clear that it is an appropriate or effective mechanisms for large-scale, population-based initiatives such as UK Biobank. This is so for several reasons. First, there is a real practical issue of achieving genuine representativeness for a heterogeneous group of 500,000 people, and, second, it belies the far broader purpose of such initiatives that are run to promote the public interest. The conclusion, however, should not be that participants should not be engaged (Gottweis and Lauss, 2010); rather it is that they should not be privileged in any engagement initiatives over other stakeholders. A preferable approach in any robust reflexive governance model would be to have a wide-ranging and on-going commitment to stakeholder, as opposed to shareholder, engagement (Hunter and Laurie, 2009).

Can the reflexive governance model work in the absence of hard law sanctions?

It is often suggested that a governance mechanism such as that deployed by UK Biobank is weak for lack of legal teeth (Gibbons, 2007). Without recourse to law, it is argued, it can quickly become ineffective and/or lose its legitimacy. This, however, is to miss the point of what a reflexive governance regime can and - just as importantly - cannot achieve. Reflexive governance is not about policing compliance, nor about risk-benefit assessment, nor is it about perpetuating tick-box approaches to top-down regulatory control.

Indeed, the irony is that if recourse to law is needed even within traditional regulatory systems then the systems have already failed. Rather, reflexive governance is about facilitating mechanisms of mutual learning in addressing genuine dilemmas as and when these arise; it is about understanding and working together to meet expectations and address challenges as these develop over time, and, over-archingly, it is about developing and applying principles and policies that remain fit for purpose throughout the lifetime of a project. I submit that the three core principles of integrity, proportionality and reflexivity provide the best basis for policy development in the biobanking context and that this can happen without recourse to law. This brings us to the final question about reflexive governance.

Can the reflexive governance model work for a range of biobanks?

It is important to separate out the experiences of UK Biobank and its Ethics and Governance Council from the lessons that might be learned about reflexive governance and the good governance framework proposed in this article. Albeit that UK Biobank is well-funded, the challenges that it faces are common to many biobanking initiatives, most of which have instituted some form of governance and oversight in addition to what is required by law. At this level of abstraction, then, there are many elements of the approaches laid out here that could be adopted and adapted for other governance mechanisms. More ambitiously, however, it is incumbent on governments, funders and regulators to consider whether bodies with the functionality of the Ethics and Governance Council might be established with a similar remit and for a range of biobanks operating under their auspices. Reflexive governance offers an effective means to address a concrete unmet need in biobanking practice.

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